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**10/566331**

I hereby certify under 37 C.F.R. § 1.10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Elvis De La Cruz

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Substitute Form PTO 1390 U.S. Department of Commerce Patent and Trademark Office

Attorney Docket Number:

04520/048002

U.S. Application Number:

Not yet assigned

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. § 371**

INTERNATIONAL APPLICATION NUMBER

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/US04/24550

July 29, 2004

July 29, 2003

TITLE OF INVENTION:

Drug Delivery Methods and Devices

APPLICANTS FOR DO/EO/US:

Michael Lewis, Bruce A. Littlefield, J. Paul Carter

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. § 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. § 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. § 371(f)).
4. ☒ The U.S. has been elected.
5. A copy of the International Application (35 U.S.C. § 371(c)(2)).  
☐ a. is transmitted herewith (required only if not transmitted by the International Bureau).  
☐ b. has been transmitted by the International Bureau.  
☒ c. Is not required, as the application was filed with the United States Receiving Office (RO/US).
6. An English language translation of the International Application into English (35 U.S.C. § 371(c)(2)).  
☐ a. is transmitted herewith.  
☐ b. has been previously submitted under 35 U.S.C. 154(d)(4).
7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3)).  
☐ a. are transmitted herewith (required only if not transmitted by the International Bureau).  
☐ b. have been transmitted by the International Bureau.  
☐ c. have not been made; however, the time limit for making such amendments has NOT expired.  
☒ d. have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3)).
9. ☐ An oath or declaration of the inventors (35 U.S.C. § 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. § 371 (c)(5)).
11. ☒ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98.
12. ☐ An assignment for recording. A separate cover sheet in compliance with 37 C.F.R. §§ 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A power of attorney and/or change of address letter.
16. ☐ Request for Deferred Examination.
17. ☐ Application Data Sheet.
18. ☐ Other items or information:
19. ☒ The following fees are submitted:

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IAP5 Rec'd PCT/PTO 27 JAN 2006

Basic National Stage Fee: \$300				\$300.00	
National Stage Search Fee  If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4): \$0  Search fee (37 C.F.R. § 1.445(a)(2)) has been paid on the international application to the USPTO as an International Search Authority: \$100  International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB: \$400  All other situations: \$500				\$0.00	
National Stage Examination Fee  If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4): \$0  All other situations: \$200				\$0.00	
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 C.F.R. § 1.492(h)).				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	18 - 20 =	0	x \$50	\$0.00	
Independent claims	3 - 3 =	0	x \$200	\$0.00	
Multiple dependent claims (if applicable)			+ \$360	\$0.00	
Application Size Fee: Additional fee for specification and drawings in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
TOTAL SHEETS	EXTRA SHEETS	Number of each additional 50 sheets or fraction thereof (round up to a whole number)	RATE		
-100=	0/50=		X\$250	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$430.00	
Reduction of 1/2 for filing by small entity, if applicable.				\$	
SUBTOTAL =				\$430.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 C.F.R. § 1.492(f)).				+	\$0.00
TOTAL NATIONAL FEE =				\$430.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. §§ 3.28, 3.31). \$40.00 per property.				+	\$0.00
TOTAL FEES ENCLOSED =				\$430.00	
				Amount to be refunded	\$
				charged	\$
<input checked="" type="checkbox"/> a. Enclosed is a check for \$430.00 to cover the total fees. <input type="checkbox"/> b. Enclosed is a check for [**\$300/\$150**] to cover the basic national stage fee; no other fees are being paid at this time. <input type="checkbox"/> c. Please charge my Deposit Account No. 03-2095 in the amount of \$[**] to cover the above fees. <input checked="" type="checkbox"/> d. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 03-2095.					
NOTE: Where an appropriate time limit under 37 C.F.R. §§ 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. § 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					

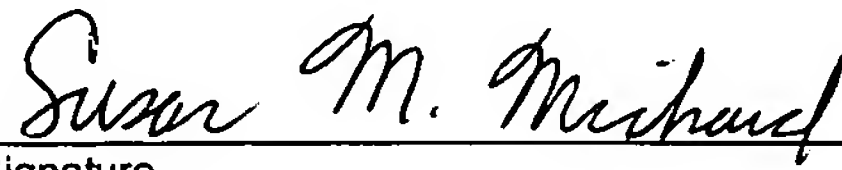
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